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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,357	02/21/2006	Moussa Youdim	YOUDIMI.1A	4865
1444 7550 66/11/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW			EXAMINER	
			DAVIS, ZINNA NORTHINGTON	
SUITE 300 WASHINGTON, DC 20001-5303			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/534,357 YOUDIM ET AL. Office Action Summary Examiner Art Unit Zinna Northington Davis 1625 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 9 March 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-60, 79-94, 96-134,136, 138 -140 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected 7) Claim(s) is/are objected to. 8) Claim(s) 1-60, 79-94, 96-134,136, 138 -140 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date \_\_\_\_\_\_\_

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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## Election/Restrictions

Pursuant to the response filed March 9, 2009, the restriction requirement mailed
January 9, 2009 is withdrawn. A new restriction requirement follows.

- 2. Claims 1-60, 79-94, 96-134,136, 138 -140 are pending.
- 3. Claims 61-78, 95, 135, and 137 have been cancelled.
- Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I:** Claims 1-60, and 99-109, drawn to a chemical compound selected from a residue that imparts a neuroproctective function in a compound and a pharmaceutical composition wherein the residue can be further restricted based upon the residue.

**Group II**: Claims 79-94, 110-128, drawn to a method for iron chelation therapy using a chemical compound of claim 1 which can be further restricted based upon the residue.

**Group III**: Claim 96, drawn to a method for iron chelation therapy using the chemical compound, 5-[4-(2-hydroxylethyl)piperazin-1-ylmethyl]-8-hydroxyquinoline.

Group IV: Claim 97, drawn to a cosmetic composition for topical application using the chemical compound, 5-[4-(2- hydroxylethyl)piperazin-l-yl

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methyl]-8-hydroxyquinoline.

**Group V**: Claim 98, drawn to a method for preservation of organs intended for transplantation using the chemical compound, 5-[4-(2-hydroxylethyl) piperazin-lylmethyl]-8-hydroxyquinoline.

**Group VI:** Claims 129, 131-132, and 134, drawn to a method for prevention of a neurodegenerative or cerebrovascular disease, condition or disorder using a chemical compound of claim 1 which can be further restricted based upon the residue.

Group VII: Claims 129, 131-132, and 134, drawn to a method for treatment of a neurodegenerative or cerebrovascular disease, condition or disorder using a chemical compound of claim 1 which can be further restricted based upon the residue.

**Group VIII**: Claims 130 and 133, drawn to a method for prevention of a neurodegenerative or cerebrovascular disease, condition or disorder using the chemical compound, 5-[4-(2-hydroxylethyl)piperazin-l-ylmethyl]-8-hydroxyquinoline.

**Group IX**: Claims 130 and 133, drawn to a method for treatment of a neurodegenerative or cerebrovascular disease, condition or disorder using the chemical compound, 5-[4-(2-hydroxylethyl)piperazin-l-ylmethyl]-8-hydroxyquinoline.

Group X: Claim 136, drawn to a method for treatment of skin disease using a chemical compound of claim 38 which can be further restricted based

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upon the residue.

Group XI: Claim 138, drawn to a method for preservation of an organ intended

for transplantation using a chemical compound of claim 38.

Group XII: Claims 139-140, drawn to a method for the treatment of a disease,

disorder, or condition using the chemical compound, 5-[4-(2-

hydroxylethyl)piperazin-l-ylmethyl]-8-hydroxyquinoline.

Group XIII: Claims 139-140, drawn to a method for the prevention of a disease,

disorder, or condition using the chemical compound, 5-[4-(2-

hydroxylethyl)piperazin-l-ylmethyl]-8-hydroxyquinoline.

5. The inventions listed as Groups I-XIII do not relate to a single general inventive

concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a common structure

is not present in which the utility is attributed.

6. This application contains claims directed to more than one species of the generic

invention. These species are deemed to lack unity of invention because they are not so

linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: the radicals defined by the residue and R. The ring

system and radicals within the definition of the residue are diverse in scope. A prior art

reference, which anticipates one member such as pyridine-4-one under 35 U.S.C. 102,

would not render obvious another member such as pyridinyl or quinoline under 35

U.S.C. 103. Accordingly, the ring systems and the radicals are independent and

patentably distinct.

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7. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If the preferred group is a method of use, a single disclosed disease state should be elected.

- 8. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:
  - (a) The inventions have acquired a separate status in the art due to their recognized divergent subject matter;
  - (b) The prior art applicable to one invention would not likely be applicable to another invention: and
  - (c) The inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.
- 9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. If the preferred invention is Group II-IV, the preferred disease or condition should be further elected.
- 10. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election

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shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

- 11. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
- 12. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

- 13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.
- 14. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. The examiner

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has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

- Due to the complexity of the restriction requirement, a written requirement is made.
- Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).
- 17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.
- The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zinna Northington Davis/ Zinna Northington Davis Primary Examiner Art Unit 1625

Znd 06.08.2009